

Below are a variety of HIPAA Topics that may be of interest.

Please be sure to note that in some cases the information presented may be the opinion of the original author. We need to be sure to view it in the context of our own organizations and environment. In some cases you may need legal opinions and/or decision documentation when interpreting the rules.

Have a great day!!!  
Ken

Topics included below are:

- [hipaalive] EDI/Pharmacy codes
- [hipaalive] Article on Clearinghouses
- [hipaalive] Privacy : Determining which uses/disclosures need authorizations
- [hipaalive] Auto log-off
- [hipaalive] covered entity and related requirements
- [hipaalive] GENERAL: Ambulance Contract
- [hipaalert] H I P A A L E R T - l i t e June 25, 2001

\*\*\*\*\* [hipaalive] EDI/Pharmacy codes

\*\*\*\*\*

\*\*\* This is HIPAALive! From Phoenix Health Systems \*\*\*

That is the buzz. I understand this will be done as a modification to the Transaction rule, but the NPRM rescinding the NDC codes has not been published.

from: [Christine.Jebesen@dhha.org](mailto:Christine.Jebesen@dhha.org)

-----Original Message-----

From: Mimi Hart [<mailto:HartAM@crstlukes.com>]

Sent: Thursday, June 28, 2001 8:13 AM

To: HIPAALive Discussion List

Subject: [hipaalive] RE: EDI/Pharmacy codes

\*\*\* This is HIPAALive! From Phoenix Health Systems \*\*\*

I apologize for the possible duplication, but am I correct in understanding that NDC codes are no longer mandated, and that J-Codes can be used in their place? Can either be used? Or can only J-Codes be used?

Mimi Hart

Mimi Hart

Project Analyst, HIPAA & DR  
Iowa Health System  
319-369-7767 (phone)

\*\*\*\*\* [hipaalive] Article on Clearinghouses

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> For everyone who wants the clearinghouse article and tape that I mentioned

> before, here ya go!

> <http://www.smed.com/hipaa/news-articles-clearinghouses.php>

> [www.himinfo.com](http://www.himinfo.com)

\*\*\* [hipaalive] Privacy : Determining which uses/disclosures need authorizations \*\*\*\*\*

It's a tad more complicated than a list of 7 items.

This is not a straightforward process. There are a lot more than 7 exceptions and there are bunches of conditions and exceptions to most of the exceptions. (Technical HIPAA term for not straightforward or easy to understand). Warning: Do not confuse me with a lawyer - do not confuse any of this advice or other common sense with legal advice - it's not.

However, here is a process that will help you figure it out.

- First read Sec. 164.508 "Uses and Disclosures for Which an Authorization is Required" (See FR 82513 for a discussion).

-Then read Sec. 164.514 "Other Requirements Relating to Uses and Disclosures of Protected Health Information", which will give you some guidelines such things as verification of identity and authority that will be applied to some of the exceptions you discover in 164.512. Make special note of the "Exercise of Professional Judgment" provision that will need to be applied to Sec. 164.512.

-Now, go back and read Sections. 164.506, 164.510 and 164.512

What you will learn is that essentially, an individual authorization is required for use or disclosure of any PHI, EXCEPT for the following (with some exceptions of course):

1) Any use and disclosure covered under Sec 164.506 "Uses and Disclosures for Treatment, Payment and Health Care Operations" ( See FR Page 82509 for a discussion)

2) Any use and disclosure covered under Sec. 164.510 "Uses and Disclosures Requiring the Individual to Have a Right to Agree or Object" (See FR 82521 for a discussion)

3) Any use and disclosure covered under Sec. 164.512 "Uses and Disclosures for Which Consent, Authorization or Opportunity to Agree or Object is Not Required" (See FR Page 82524 for a discussion) A summary of those permitted disclosures as follows:

- a. Public health authority authorized by law to collect information for the purpose of preventing or controlling disease
- b. Public health authority authorized by law to collect information on child abuse
- c. Report adverse events to FDA
- d. Product tracking (if required by the FDA)
- e. Enable product recalls
- f. Post marketing surveillance at the direction of the FDA
- g. Notify an individual of exposure to a communicable disease
- h. At the request of an employer for the purpose of
- i. Evaluating work related injury or illness
- ii. Related to medical surveillance of the workplace
- iii. Certain other instances relating to workers compensation and workplace health and safety
- iv. Notify an employer about certain issues required by law
- i. Reports about victims of abuse, neglect or domestic violence (lots of conditions here)
- j. Disclosures to prevent serious harm to an individual (lots more conditions)
- k. Health oversight activities (lots and lots of conditions and exceptions)
- l. Respond to court orders, subpoena's and other judicial requests (some very subtle and tricky conditions)
- m. Disclosure to law enforcement - under very specific circumstances and disclosure of limited amounts of information.

Examples:

- i. Reporting a crime on the premise
- ii. Identification of suspects, missing persons, material witnesses.
- iii. Information about victims of a crime
- iv. Reporting a crime in an emergency
- v. Reporting child abuse
- vi. If the victim of a crime is dead - you do not need their permission to disclose that fact to law enforcement.
- n. If the patient is dead - you do not need their permission to disclose PHI to the funeral director or the coroner
- o. If the patient is dead - for the procurement of their organs for transplant - (Note: This does not mean you can remove and distribute organs willy nilly)
- p. Research - approved by an IRB or private Privacy Board (lots conditions, including the makeup of the IRB/Privacy Board)
- q. Military and veterans organizations for certain uses. Includes foreign military personnel
- r. National intelligence activities (now there's a oxymoron for you)

- s. Protective services for the President
- t. Department of State for certain situations
- u. Correctional institutions
- v. Government programs
- 4) Some uses and disclosures contained in Sec.164.514
  - a. Certain marketing communications that are for the furtherance of patient care (e.g. prescribing non-generic drugs, recommending facilities, referrals to other providers, etc.) - (subject to conditions)
  - b. Use by the covered entity in fund raising (subject to conditions)
  - c. For underwriting and related purposes - (subject to conditions)

I hope this helps.  
Thanks,

Tom Hanks  
37W542 High Point Court  
St. Charles, IL 60175

\*\*\*\*\* [hipaalive] Auto log-off \*\*\*\*\*  
\*\* This is HIPAALive! From Phoenix Health Systems \*\*

No. The proposed Security rule specifies auto log-off, but it is up to the covered entity to determine what the timeframe would be - and it may vary depending on the location of the computer. The auto log-off in a "public area" (an area accessible by multiple staff, cleaning people, perhaps salespeople) could be shorter than that in a provider's private office.

Christine Jensen  
HIPAA Project Manager - Denver Health

\*\*\*\*\* [hipaalive] covered entity and related requirements  
\*\*\*\*\*  
\*\*\* This is HIPAALive! From Phoenix Health Systems \*\*\*

Leah,

It sounds like you understand what I am asking. Our legal entity is the County, but in my mind our health care provider is the Health Services Agency.

What argument can I use to support the claim that the use of the term "covered entity" in the transaction rules refers to the "legal entity". The transaction rules do not use the term legal entity. I am a Systems Analyst / Project Manager by trade, so there are probably a lot of legal nuances

related to federal regulations that I am unaware of. I could be taking the rules too literally when they say the covered entity is the "health care provider", "health plan", or "health care clearinghouse".

Without getting into a long explanation of how our County is set up, there do appear to be some HIPAA covered transactions used within the County that are not executed by the Health Services Agency. If the Transaction Rules should be applied to the County, then I believe those other transactions should be in the standard format. If the Transaction Rules apply to the Agency, then those other transactions are probably not required to use the standard format.

I think I am going to recommend that all HIPAA covered transactions used within the County be in the standard format, unless legal justification to exempt certain transactions can be provided. But for curiosity's sake, I would still be interested in knowing the precise interpretation (if there is one), of the term covered entity, as it is used in the Transaction Rules.

Thanks for your help.

\*\*\* This is HIPAAlive! From Phoenix Health Systems \*\*\*

Heather,

Thanks for taking the time to help me think this through. I follow what you are saying, but I'm not sure I can make the jump between your first paragraph and second paragraph. The hybrid entity concepts are embedded in the Privacy Rules, and therefore do not technically apply to the TCS Rules, or to the General Administrative Requirements in Part 160.

Our Agency is a health care provider, and it does use some of the covered electronic transactions, therefore it definitely fits the definition of a covered entity, as described in section 160.103. So when the TCS Rules came out, I understood the Agency to be the covered entity. However, when the Privacy Rules brought up the hybrid entity definition, I changed my thinking to believe the County is the covered entity, and hybrid entity, and the Agency is a health care component - just as you describe.

I then realized the hybrid entity concepts do not in any way state or imply that they should be used when interpreting any of the other HIPAA Rules. In fact, the Privacy Rules in 164.504(b) and (c) seem to be specifically restricting their application to the Privacy Rules, e.g. Subpart E of Part 164 - Privacy of IIHI. If that is what the writers of the Rules intended, then I am left to think the Agency is the covered entity with respect to the TCS Rules, and the County is the covered entity with respect to the Privacy Rules.

So when the TCS Rules state that standard transactions must be used, "If a covered entity conducts with another covered entity (or within the same

covered entity)", we could be talking about a different set of exchanges based on whether "covered entity" is referring to the Agency or the County.

The Proposed Security Rules do not reference the term covered entity or hybrid entity. They simply indicate, in section 142.102, what entities the Security Rules apply to, and under what conditions. Based on the explanation provided, I again would interpret the Security Rules to mean that the Agency is the covered entity, even though the term covered entity is not actually used.

I suppose its possible I am over analyzing the rules, and I don't mean to waste anyone's time, but I have been asked to provide my opinion on how the rules might affect transactions and information exchanges between our County's health care components and non-health care components. How the hybrid entity concept is interpreted with respect to the TCS and Security Rules impacts what my answer will be.

Thanks again for your help.

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Jim -

Also, regarding the Transactions Rule, another consideration is the health plan exception for government funded programs found in the definitions (which were amended when the privacy rule was finalized) at 160.103 and comments at pg. 82479. The exception is for government funded programs (other than those specifically listed like Medicaid) whose principal purpose is other than provision or payment of health care; or who provide health care directly or by grant.

You may still be a health care provider or clearinghouse, but the more onerous transaction rule requirements of a health plan (capacity to accept/send the standard transactions) would not apply to the parts of your organization that meet the exception.

"government funded program" is not defined, although there are some examples in the comments, so deciding what is a program is an interesting challenge.

Leah Hole-Curry, JD, HIPAA Legal Officer  
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One additional question for a hybrid entity is whether the data transactions taking place within the entity, between the health care component and the

rest of the entity, are really HIPAA transactions or simply benign exchanges of data. That is, the purpose of the transaction is important.

Bill MacBain  
MacBain & MacBain, LLC  
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\*\*\* This is HIPAAlive! From Phoenix Health Systems \*\*\*

Jim:

Wanted to help clarify your structural issues under HIPAA. After determining one is either a health care provider, health care clearing house or health plan as defined by HIPAA and that health information is transmitted in an electronic form, the issue becomes -- yes, I am a covered entity, but what type of structural covered entity am I? The options are: 1) single covered entity; 2) organized health care arrangement; 3) affiliated covered entity; 4) hybrid entity or 5) combinations of the above (e.g., our company is designating themselves as an affiliated covered entity, but we have hybrid entities and organized health care arrangements within that structure). A health care component is not really a structure, it is a term of art used to refer to the portion of the entity that conducts covered functions (as described below by Tom). So, in your situation, the County is a covered entity with the structural status of a hybrid entity and the Agency is the health care component of the hybrid entity that performs the covered functions and is required to comply with HIPAA rules.

As to the TCS issue, I think you answered your own question -- "If a covered entity conducts with another covered entity (or within the same covered entity)" -- the Agency is the health care component that is within your County covered entity and use of a standard transaction is required unless some other exception applies.

Hope this helps.

Heather Hilliard  
Adventist Health System  
407=975-1400

-----Original Message-----

From: Jim Watkins [<mailto:RCRMC.JWATKINS@co.riverside.ca.us>]

Sent: Monday, June 18, 2001 1:05 PM

To: HIPAAlive Discussion List

Subject: [hipaalive] RE: TCS: Hybrid Entity and TCS Rules

\*\*\* This is HIPAAlive! From Phoenix Health Systems \*\*\*

Tom,

Thanks for the feedback. I represent a Health Services Agency, which is part of a County government entity. I believe the County is a hybrid entity, and therefore a covered entity with respect to the Privacy Rules. My understanding of the Privacy Rules make the County the covered entity, and the Agency a health care component. Although most of the Privacy Rules are to be applied to the health care component, rather than the covered entity, the Agency is not technically considered a covered entity under the Privacy Rules.

Looking at the TCS Rules though, it appears the Agency is the covered entity, since there is no such thing as a hybrid entity under the TCS Rules. So under the Privacy Rules the County is the covered entity, and under the TCS Rules the Agency is the covered entity. This is significant because the TCS Rules would apply differently based on whether the County or the Agency is the covered entity. For example, the TCS Rules state that, "... if a covered entity conducts with another covered entity (or within the same covered entity) ... a transaction for which the Secretary has adopted a standard ... the covered entity must conduct the transaction as a standard transaction." Depending on whether the County or Agency is the covered entity, could impact what transactions within the County are covered.

Does you know if there are any plans to apply the hybrid entity concepts across all HIPAA Rules?

Any additional feedback would be appreciated. Thanks.

>>> [TomHanks@ameritech.net](mailto:TomHanks@ameritech.net) 6/13/01 9:40:44 PM >>>  
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With a hybrid entity, any of their health care components that would be a covered entity under HIPAA if they stood alone, are treated as a covered entity under HIPAA.

- 1) If the main entity would not be a covered entity under HIPAA, they are not a covered component of the hybrid entity.
- 2) However, there has to be a firewall between the covered components and the non-covered components to protect the PHI.
- 3) Even if the main entity is not a covered entity, they are probably the responsible entity.

Note: If most of the activities of a hybrid entity are related to health care, then the entire entity and all of its components are treated as a covered entity.



See FR 82502 for a discussion of hybrid entities.

Thanks,

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-----Original Message-----

From: Jim Watkins [<mailto:RCRMC.JWATKINS@co.riverside.ca.us>]  
Sent: Tuesday, June 12, 2001 7:17 PM  
To: HIPAAlive Discussion List  
Subject: [hipaalive] TCS: Hybrid Entity and TCS Rules

\*\*\* This is HIPAAlive! From Phoenix Health Systems \*\*\*

Once a hybrid entity organization identifies its health care components, it is my understanding the main organization is technically still considered the covered entity, under the Privacy Rules, but it is permissible to apply most of the Privacy Rules to only the health care components as if they were the covered entity. But since the hybrid entity and health care component definitions only pertain to the Privacy Rules, what is considered the covered entity when interpreting the TCS Rules? Since there is no such thing as a hybrid entity in the TCS Rules, is the main organization the covered entity, or would the components of the organization that provide the health care services be the covered entities? Does anyone know if there are plans to change the hybrid entity rule so it applies to all of the HIPAA regulations?

---

Jim Watkins  
HIPAA Project Manager  
Riverside County Health Services Agency  
[RCRMC.JWatkins@CO.Riverside.CA.US](mailto:RCRMC.JWatkins@CO.Riverside.CA.US)

\*\*\*\*\* [hipaalive] GENERAL: Ambulance Contract  
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\*\*\* This is HIPAAlive! From Phoenix Health Systems \*\*\*

1) Providers sharing PHI for the purpose of treatment do not create the need for a BAC.

- 2) If the providers are part of an Organized Health Care Arrangement, information can be shared for the purpose of treatment, payment and health care operations.
- 3) Ambulance EMTs are simply providers cooperating with other providers in the treatment of an individual. This activity does not create a business associate relationship - no BAC required.
- 4) However, for intra-facility transportation, if the ambulance company bills the hospital for transportation and the hospital then bills the individual, then the ambulance is providing a service to the hospital and a BAC would be required.
- 5) If the ambulance performs the transportation and bills the patient, then they are providing the service to the patient and are then merely cooperating in the treatment and not providing a service to the hospital - no BAC would be required.
- 6) Simply being the conveyer of information delivered between providers for the purpose of treatment would not require a BAC

See FR Page 82475

"In the final rule, we change the definition of "business associate" to clarify the circumstances in which a person is acting as a business associate of a covered entity. The changes clarify that the business association occurs when the right to use or disclose the protected health information belongs to the covered entity, and another person is using or disclosing the protected health information (or creating, obtaining and using the protected health information) to perform a function or activity on behalf of the covered entity.

Also FR Page 82476

"This change is consistent with changes made in the final rule to the definition of health care operations, which permits covered entities to use or disclose protected health information not only for their own health care operations, but also for the operations of an organized health care arrangement in which the covered entity participates."

-and

"We also add language to the final rule that clarifies that the mere fact that two covered entities participate in an organized health care arrangement does not make either of the covered entities a business associate of the other covered entity. The fact that the entities participate in joint health care operations or other joint activities, or pursue common goals through

a joint activity, does not mean that one party is performing a function or activity on behalf of the other party (or is providing a specified services to or for the other party).

-and

"For example, when a health care provider discloses protected health information to health plans for payment purposes, no business associate relationship is established. While the covered provider may have an agreement to accept discounted fees as reimbursement for services provided to health plan members, neither entity is acting on behalf of or providing a service to the other.

"Similarly, where a physician or other provider has staff privileges at an institution, neither party to the relationship is a business associate based solely on the staff privileges because neither party is providing functions or activities on behalf of the other. However, if a party provides services to or for the other, such as where a hospital provides billing services for physicians with staff privileges, a business associate relationship may arise with respect to those services."

Thanks,

Tom Hanks  
37W542 High Point Court  
St. Charles, IL 60175

\*\*\*\*\* [hipaalert] H I P A A L E R T - l i t e June 25, 2001  
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H I P A A L E R T - l i t e June 25, 2001

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H I P A A n e w s

\*\*\* Financial Privacy Notices Criticized \*\*\*

Facing a July 1 deadline to comply with new privacy protections, financial firms have sent out an estimated half a billion privacy notices to their customers. Consumer groups said they would ask regulators to step in to make them easier to comprehend.

<http://www.hipaadvisory.com/news/index.htm#yahoo0621>

\*\*\* TRUSTe Launches Privacy Symbols Initiative \*\*\*

TRUSTe announced last week that it has launched an initiative to build a broad coalition to develop unified, consumer-friendly privacy policy symbols and labels. The new standard iconography is intended to improve consumer understanding of how their personal information is used.

<http://www.hipaadvisory.com/news/2001/truste0619.htm>

\*\*\* EU approves standard rules for non-EU data transfer \*\*\*

The European Commission (EU) said last week it had adopted standard contract clauses that would guarantee secure exchange of customers' data between the EU and other countries. By adopting such model clauses, companies based outside the 15-nation bloc would immediately comply with the EU legislation and avoid potential lawsuits.

<http://www.hipaadvisory.com/news/index.htm#yahoo0618>

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H I P A A l a t e s t

NEW IN HIPAACTION:

- Security, Houston floods teach IT managers readiness lessons  
One of the major lessons learned from Tropical Storm Allison was that IT staff members should have been included as integral members of the medical center's emergency command center.

<http://www.hipaadvisory.com/action/Security/index.htm#houston>

NEW IN HIPAATECH:

- Virtually Insecure:  
If you're going to extend access to your network to telecommuters, you'd better have the proper security measures in place.

<http://www.hipaadvisory.com/tech/index.htm#iweek0611>

NEW IN HIPAAUDIO:

- Legally HIPAA! A Summer Audioconference Series  
with Steve Fox, Esq., author of HIPAAAdvisor  
July 18: Handling Chain of Trust & Business Associate Agreements  
August 22: Developing Privacy/Security Policies and Procedures  
<http://www.hipaadvisory.com/order/legal/index.cfm>

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HIPAAAlert-lite is our weekly version of HIPAAAlert, Phoenix Health Systems' acclaimed monthly email newsletter. HIPAAAlert-lite is published each Monday to keep subscribers abreast of breaking news and industry developments in healthcare privacy and security.

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Our Other HIPAA resources:

Web site: <http://www.hipaadvisory.com>

Discussion List: <http://www.hipaadvisory.com/live/>

Weekly Awareness Note: <http://www.hipaadvisory.com/notes/>

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